REMARKS

Applicants have received and reviewed the Office Action dated February 19, 2010. By way of response, Applicants have canceled claim 11 without prejudice and present the following remarks. Applicants have amended claims 1, 7, 9, 10, and 33 and present new claims 34-36. No new matter has been added. Claims 1, 6-7, 9-10 and 12-36 are pending.

Applicants submit that the amended claims are supported by the specification as filed. In particular, support for the recitation of "flowable" in claims 1 and 33 can be found throughout the specification as filed including at least at page 18, lines 1-22.

For the reasons presented below, Applicants respectfully submit that the amended claims are in condition for allowance, and notification to that effect is earnestly solicited.

Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 7, 9-11, 21, 26, 29, 30 and 33 under 35 U.S.C. § 103(a) over Halskov, WO 81/02671 in view of Valducci, US 2002/0034541. The Examiner rejected claims 6 and 27-28 under 35 U.S.C. 103(a) over Halskov in view of Valducci and further in view of Augsburger et al., US 2002/0177579. Applicants respectfully traverse these rejections.

The Halskov reference discloses a sustained release tablet that is made up, according to calculations in the Office Action, of granules 78 wt-% mesalazine, 8 wt-% polyvinylpyrrolidone, and 14 wt-% ethylcellulose coating. This reference discloses that all of the mesalazine is released from this tablet in 12 hours at pH 7.5. This reference discloses a tablet as dosage form, the granules are pressed to form the tablet. The tablet also includes other ingredients. The tablet is administered to the patient.

In contrast, the presently claimed invention relates to formulation for oral administration that is in the form of flowable granules, not a tablet. In an embodiment, the granules of the presently claimed invention includes 94.3% mesalazine, 4.7% polyvinylpyrrolidone, and 1% ethylcellulose. These coated granules "when suspended in an aqueous buffer at pH 7.5, release the mesalazine according to a release profile in which:

a) 5-25% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules is released after 15 min;

b) 30-70% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules is released after 90 min; and

c) 75-100% of the total amount of mesalazine or pharmaceutically acceptable salt thereof in the granules is released after 240 min".

This is a significantly longer release profile than one might expect based on the cited Halskov reference.

According to Halskov, it takes only 12 hours for the two step process of: 1) dissolving the tablet thereby releasing coated granules containing 14 wt-% coating into the solution; and 2) dissolving the coated granules containing 14 wt-% coating to release 100% of their mesalazine. In marked contrast, even without having to include time for a tablet to dissolve, the presently claimed granules can achieve almost as long a dissolution profile when containing only $1/14^{th}$ as much coating (1%). It takes 4 hours or more to dissolve the presently claimed granules to release 100% of their mesalazine. At least $1/3^{rd}$ the time from only $1/14^{th}$ as much coating.

Thus, the presently claimed granules provide an unexpectedly long release profile in view of the Halskov reference.

The secondary references do not remedy the shortcomings of the primary reference. The secondary Valducci reference discloses more complicated coatings to achieve "multiphasic" release. The Augsberger reference discloses complicated coated mixtures that achieve a desired release profile.

Accordingly, based on the foregoing differences, Applicants submit that the cited references neither teach nor suggest the presently claimed granulate, and withdrawal of this rejection is earnestly solicited.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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